IN THE UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

RUTH SMITH, Individually and as Widow for the Use and Benefit of Herself and the Next Kin of Richard Smith, Deceased,	)	
Plaintiff,	)	Civil No. 3:05-0444
	)	Judge Aleta A. Trauger
v.	)	(Dist. Of MA No. 1:05-cv-11515PBS)
PFIZER, INC., *et al.*,	)	
Defendants.	)	

MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION *IN LIMINE* TO STRIKE THE DEPOSITION TESTIMONY AND AFFIDAVIT OF CYNTHIA MCCORMICK AND TO PRECLUDE DEFENDANTS FROM UTILIZING THE DEPOSITION OF CHARLES TAYLOR AT TRIAL

Defendants Pfizer Inc and Warner-Lambert Company LLC (collectively, "Pfizer" or "Defendants") respectfully submit this memorandum in opposition to Plaintiff's motion to exclude evidence related to Dr. Cynthia McCormick. Because the testimony of Dr. McCormick does not constitute "expert testimony," there is no basis for its exclusion. Further, because Defendants currently intend to call Dr. Charles Taylor to testify live during trial, Plaintiff's motion to exclude his deposition testimony is premature.

ARGUMENT

I. Dr. McCormick Is Not an Expert Witness

Dr. McCormick's testimony in the context of this litigation is purely factual – a finding supported by the assessments of Judges Saris and Young in response to similar arguments by plaintiffs in other MDL cases. Dr. McCormick is a medical doctor who worked for the FDA from July 1991 to October 2002. (Ex. A, Dr. Cynthia McCormick Dep. at 100:15-22.)[1] For about the first five or six years of her employment, she was a medical officer (or clinical

[1] All exhibits are attached to the accompanying Declaration of Mark S. Cheffo.

reviewer) and her responsibilities involved reviewing investigational new drug applications. (*Id.* at 101:3-22.) This review process involved attendance at meetings, review of safety and clinical study reports, any many other responsibilities related to "shepherding a drug through th[e] process prior to approval." (*Id.* at 103:2-8.) Of note, she performed work as a medical officer in relation to the new drug application for Neurontin. (*Id.* at 104:18-23.) Later in her career, she was promoted to a divisional director within the FDA, during which time she also was involved with the FDA's approval of Neurontin for post-herpetic neuralgia. (*Id.* at 106:15-20.) After leaving the FDA, she has worked as a consultant. In this litigation, she has been questioned about her personal involvement in the FDA's review of Neurontin at different stages. Because Dr. McCormick's testimony involves information within the scope of her personal knowledge and does not require the application of "scientific, technical, or other specialized knowledge," Fed. R. Evid. 702, it does not constitute "expert testimony," pursuant to Rule 26(a)(2), and therefore an expert report was not required.

As the advisory committee has explained, the written report requirement applies only to expert witnesses "who are retained or specially employed to provide . . . testimony [under Rule 702 of the Federal Rules of Evidence with respect to scientific, technical, and other specialized matters] in the case or whose duties as an employee of a party regularly involve the giving of such testimony." Fed. R. Civ. P. 26(a)(2), 1993 advisory committee's note. As such, the Sixth Circuit has found that Rule 26(a)(2) does not require an expert report where a witness did not "form[] [her] opinion at the request of . . . counsel." *Fielden v. CSX Transportation*, 482 F.3d 866, 869 (6th Cir. 2007); *see also Gomez v. Rivera Rodriguez*, 344 F.3d 103, 113 (1st Cir. 2003) (holding that "a party need not identify a witness as an expert so long as the witness played a personal role in the unfolding of the events at issue and the anticipated questioning seeks only to elicit the witness's knowledge of those events"). "'The determinative issue is the scope of the proposed testimony.'" *Fielden*, 482 F.3d at 871 (quoting *Wreath v. United States*, 161 F.R.D. 448, 450 (D. Kan. 1995)). In other words, even where a witness happens to have a special expertise, that does not mean she is rendering an expert opinion for the purposes of litigation

where she will merely testify about matters "within the normal range of [her] duties." *Fielden*, 482 F.3d at 870 (quoting *Martin v. CSX Transp., Inc.*, 215 F.R.D. 554, 557 (S.D. Ind. 2003)); *Gomez*, 344 F.3d at 113 (finding that a report is not required for a "percipient witness who happens to be an expert").

Thus, in *Fielden*, the Sixth Circuit held that a witness, who had specialized knowledge of the matters at issue, should have been permitted to testify without filing a written report because he "formed his opinions" before – and not in response to – the lawsuit. 482 F.3d at 869. Here also, though Dr. McCormick has expertise in the medical and regulatory field, at her deposition she testified about "personal knowledge acquired before any litigation had begun" – that is, the regulatory and developmental history of Neurontin. *See id.* The designated deposition testimony of Dr. McCormick concerns her personal knowledge of the FDA's review process of Neurontin, what conclusions were reached in that process, and the reasoning behind those conclusions.[2] For example, Plaintiff relies upon a statement in the FDA's 1992 Combined Medical-Statistical Review of Neurontin to argue that Pfizer was on notice of an association between Neurontin and suicide in 1992. Dr. McCormick was the author of the statement upon which Plaintiff relies. (McCormick Dep. at 118:16-119:12.) Defendants seek to offer Dr. McCormick's deposition testimony to explain this statement and put in the context. For example, at her deposition, Dr. McCormick explained that Plaintiff's counsel has mischaracterized her previous statement. (*See* McCormick Dep. at 119:13-120:11.)

While Dr. McCormick's testimony may include some ostensibly technical statements,

[2] The designated portions of Dr. McCormick's testimony include some testimony regarding her views of the FDA's 2008 analysis of the association between anti-epileptic drugs and suicide. This represents only a small portion of her testimony and this line of questioning was initiated by Plaintiff's counsel, not Defendants. (McCormick Dep. at 29:10-31:15; 32:15-35:22.) To the extent that Plaintiff is permitted to play such testimony to the jury, she cannot object to Defendants' playing their questioning of Dr. McCormick on this same topic on the grounds that it calls for expert opinion. Such testimony is admissible under the rule of completeness. *See* Fed. R. Evid. 106. Further, Dr. McCormick's response to Defendants' questions on this topic was grounded by her knowledge, as a fact witness, of the historical data submitted in connection with the Neurontin new drug application and supplemental new drug application. (McCormick Dep. at 129:4-14.)

such testimony was derived from her personal knowledge as to what evidence was considered by the FDA during the review process. In other words, Dr. McCormick is not being called to offer any opinion she might hold today regarding whether there is an association between Neurontin and suicidal behavior. Rather, her deposition testimony concerns historic events that she participated in. For example, Plaintiff's objection to the following portion of Dr. McCormick's testimony is baseless:

> Q: *While you were employed at the FDA from 1991 to 2002*, did you ever conclude that Neurontin increases the risk of or is causally associated with any type of suicidal thinking or suicidal behavior?
>
> . . . .
>
> A: In the documents that I reviewed, *both in my responsibility as a medical officer in epilepsy and also in my review of the Neurontin application for post-herpetic neuralgia*, I did not see anything that would suggest an increased risk of suicidality.

(McCormick Dep. at 107:5-17 (emphasis added).) In the above-quoted section, Dr. McCormick's testimony is explicitly restricted to the then-existing circumstances she considered while working for the FDA and, therefore, it constitutes a recollection of past events, which is not expert testimony. In fact, in response to a question by Plaintiff's counsel about neurotransmitters at her deposition, Dr. McCormick made clear: "I have not been asked to discuss anything besides the record and I think that if you need an expert witness to do neurochemistry with you . . . I'm not your person." (*Id.* at 65:23-66:3.) As Judge Saris observed during the pretrial conference in a previous case in the MDL, Dr. McCormick "can testify about factually what she did or she didn't do" and "about what her opinion was at that particular moment in time." (Ex. B, *Bulger* Pre-trial Conference Tr. at 118:18-25.) Likewise, Judge Young declined to "treat [McCormick] as an expert" in response to a similar motion filed when Dr. McCormick was set to deliver analogous testimony in the *Shearer* trial. (Ex. C, *Shearer* Trial Tr. at 71:15-17.) Thus, Dr. McCormick's personal knowledge of these matters constitutes fact testimony, which is not subject to the requirements of Rule 26(a)(2).[3]

[3] Plaintiff argues that there is an inconsistency between Dr. McCormick's affidavit and the statement that she made in 1992. (Pl.'s Memo. [93] at 3.) As noted above, Dr. McCormick disagrees *(cont'd)*

Rather than addressing the actual substance of the disputed testimony, which is the proper focus, Plaintiff conclusorily asserts that "[i]t is quite clear that Cynthia McCormick is not just a fact witness in this litigation." (Pl.'s Memo. [93] at 2.) As the Sixth Circuit has made clear, however, the touchstone for this inquiry is not the status of the witness, but, rather, "the scope of the proposed testimony." *Fielden*, 482 F.3d at 871 (citation omitted). As such, Plaintiff's argument that Dr. McCormick should be peremptorily branded as an expert is incorrect under applicable law.

Furthermore, Plaintiff's chief support for her assertion that Dr. McCormick is an expert is that Pfizer coordinated with her and compensated her for her time and expenses. However, Pfizer merely reimbursed her in the amount of her standard consulting fee in order to make up for the loss of income she otherwise would have made, if she had not needed to prepare for and provide testimony by affidavit and deposition in this case. (*See* McCormick Dep. at 39:7-11.) As such, the fact that Pfizer compensated Dr. McCormick for her time has no bearing on whether she is a fact or expert witness because witnesses that deliver both types of testimony may receive compensation for testifying and preparing to testify. For example, courts have recognized that fact witnesses may be compensated for their lost time and income beyond the $40 witness fee provided in 28 U.S.C. § 1821. *See, e.g.*, *Prasad v. MML Investors Servs.*, 04 Civ. 380, 2004 WL 1151735, at *5 (S.D.N.Y. May 27, 2004) (observing that federal courts "are generally in agreement that a witness may properly receive payment related to the witness' expenses and reimbursement for time lost associated with the litigation"); *id.* at *7 (holding that reimbursement of fact witness' time at his normal hourly rate was not excessive or unreasonable); *see also Centennial Mngt. Servs., Inc. v. Axa Re Vie*, 193 F.R.D. 671, 682 (D. Kan. 2000)

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with Plaintiff's characterization of her prior statement. Regardless, the issue of consistency has nothing to do with whether she will be presenting "expert testimony," which is Plaintiff's only argument for exclusion. Furthermore, it would be unfair to allow Plaintiff to admit Dr. McCormick's 1992 statement into evidence while precluding her from testifying and explaining what she actually meant by that statement and its context.

("[O]ccurrence witnesses may be reasonably compensated for time spent in attending a deposition or trial; for time spent in pretrial interviews with the lawyer in preparation for testifying; and for time spent in reviewing and researching records that are germane to his or her testimony."); *Morgan v. U.S. Express, Inc.*, No. 03-88-1, 2006 WL 278398, at *4 (M.D. Ga. Feb. 3, 2006) (finding that the fee statute related to fact witnesses only "sets forth the minimum amount a fact witness is entitled to receive, [and] there is nothing in the statute prohibiting the parties from agreeing to pay a higher amount").[4] In this case, Dr. McCormick was being asked to provide testimony regarding events that occurred several years in the past and, as a result, undertook the time consuming process of reviewing the historical record to refresh her recollection. Under such circumstances, it was appropriate to compensate her for the reasonable value of her time. For example, in *Roemmich v. Eagle Eye Development, LLC*, No. 1:04-cv-079, 2006 WL 3833433 (D.N.D. Dec 29, 2006), fees were paid to a former federal official who had supervised the development projects at issue in the litigation. *See id.* at *4. The court noted that most jurisdictions allow "compensation for time spent in preparation for, and testifying at, trial or deposition, at least when the circumstances warrant such compensation." *Id.* at *5. As the court explained:

> One of these circumstances is when a fact witness has to spend significant time reviewing records in order to testify. Permitting additional compensation in this situation is fair to the witness. Also, it promotes justice to the extent it results in testimony that is more accurate and meaningful and does not limit the parties to calling only those wit-nesses who have the resources and the willingness to devout significant time without compensation.

Id.

In any event, Plaintiff's emphasis on Dr. McCormick's compensation is a red herring

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[4] *See also* ABA Ethics Op. 96-402 (Aug. 2, 1996) (observing that attorneys may "compensate a non-expert witness for the reasonable value of the time expended by the witness while preparing for or giving testimony at a deposition or at a trial," and what constitutes a reasonable amount of compensation "is relatively easy to determine in situations where the witness can demonstrate to the lawyer that [she] has sustained a direct loss of income because of [her] time away from work – as, for example, loss of hourly wages or *professional fees*" (emphasis added)).

because whether Dr. McCormick's testimony falls into the fact or expert category is determined by the substance of the testimony. *See Fielden*, 482 F.3d at 871. As such, there is no basis for excluding Dr. McCormick's factual testimony.

II. Plaintiff's Motion Should be Denied As To Dr. Taylor

Defendants currently intend to present Dr. Taylor as a live witness. Therefore, Plaintiff's motion with regard to Dr. Taylor's deposition testimony is premature. However, as Plaintiff's counsel is aware, Dr. Taylor has been undergoing treatment for leukemia, including chemotherapy, and he lives in Michigan. (Ex. D, Taylor Dep. at 8:19-9:18.) Should circumstances arise that would prevent Dr. Taylor from traveling to Nashville during the trial for medical reasons, Defendants should be permitted to present into evidence his deposition testimony due to the witness's unavailability. *See* Fed. R. Civ. P. 32(a)(4)(C); Fed. R. Evid. 804(b)(1). In the event such a contingency occurs, Defendants will provide the Court with any requested documentation in order to establish unavailability.

CONCLUSION

For all of the foregoing reasons, Pfizer respectfully requests that the Court deny Plaintiff's motion to exclude evidence related to Dr. McCormick and Dr. Taylor.

Dated: April 27, 2010

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this the 27th day of April 2010, I electronically filed the foregoing document with the Clerk of the Court, United States District Court for the Middle District of Tennessee, using the CM/ECF system. True and correct copies of the foregoing documents are being served via the Court's CM/ECF system on the following:

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